REMARKS

Claims 1, 2 and 12-15 are pending in the application. The examiner has rejected these claims over the Cohn reference, US 6,211,249, having apparently withdrawn the Final rejection based on the Casey reference, US 4,716,203.

THE REJECTION UNDER 35 U.S.C. § §102 and 103

The examiner has held that Claims 1, 2, and 15 are unpatentable over the Cohn reference, US 6,211,249 under 35 U.S.C. 102(b). He has analyzed the reference and found that polymeric compositions of an A-B diblock are taught wherein the A unit is derived from among a list of monomers, glycolic acid and ε-caprolactone, and the B unit can be polyethylene oxide. The molecular weight of the reference polymer can be between 550 to 5000 or more. This teaching, it is alleged, anticipates Applicants' claims 1, 2, and 15. Furthermore, under §103(a), the examiner holds Claims 1 and 12-14 unpatentable as obvious over the same Cohn reference, US 6,211,249.The apparent motivation to make the Applicants' claimed compositions is thatr the prior art has suggested and/or taught compositions useful in medical applications.

Applicants respectfully traverse the rejection. The reference does not disclose or suggest the claimed invention. The claimed invention is directed to diblock copolymers of formula A-B wherein: the polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and the polymer block B represents a polymer comprising at least two different monomers selected from glycolic acid, propiolactone, γ-butyrolactone, δ-valerolactone, γ-valerolactone, ε-caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, ε-lactone, 1,5-dioxepan-2-one wherein the diblock copolymer is liquid at a temperature below 50°C. Although this bears some superficial resemblance to the prior art, on deeper analysis, the conclusion does not hold. Applicants first of all, are providing a liquid copolymer; the prior art is clearly a solid composition, albeit water-soluble (column 36, line 4-34), or viscous, (Eample 1) useful in topical wound dressings. The compositions have properties that prevent adhesions and promote wound healing. The actual compositions prepared in the Cohn reference are quite different from those taught in the instant application.

In Cohn, there is general information on the composition of block A and block B and general information on the molecular weight of the different units as referred to by the Examiner in the OA on pages 2 and 3, but there is no disclosure of the instant diblock polymers per se.

The Cohn teaching relates to diblock copolymers that areused as building blocks for more complex polymeric structures. For these diblock copolymeric buiding blocks, only lactide as a monomer in the diblock copolymer (apart from the hydrophilic polymer PEG) is described. Lactide is not taught in the instant invention as being a possible monomer for the polymer block B. In other words, the actual teaching of Cohn and its examples do not teach any diblock copolymers claimed in the instant application. Applicants provide their block B from two different monomers (not encompassing lactide). There is no explicit teaching of Applicants' invention in the Cohn reference.

Even more relevantly, Cohn describes copolymers which are able to provide a barrier to prevent adhesions to form subsequent to medical procedures such as surgery or which are suitable to form surgical articles or which can control the release of bioactive agents in the body. No disclosure is made of micelle forming properties. The disclosed utility in Cohn is remote from that of Applicants, and accordingly, a holding of identical inherent properties is not sustainable as a rejection.

The present invention relates to diblock copolymers which are able to form stable micellar solutions and which are able to incorporate drugs without the need of complex incorporation techniques such as for example the use of organic solvents, followed by their evaporation, or the use of dialysis. These copolymers have self-emulsifying properties. They are able to form spontaneously micellar solutions in water, possibly due to a balance between the hydrophilic and the hydrophobic part of the diblock copolymers.The diblock copolymers of the present invention are characterized by a hydrophilic part which has a restricted molecular weight, < 1,000. This implies that also the hydrophobic part of the copolymers is relatively restricted in molecular weight, therefore, the copolymers are characterized by being liquid below 50°C.

Surprisingly, Applicants found that notwithstanding the fact that the hydrophilic part of the copolymers is relatively small and notwithstanding the fact that the total weight of the copolymers is relatively small, they are still able to form stable micelles.

Based on Cohn, one skilled in the art could not predict that such relatively small copolymers could be able to form stable micelles. More relevantly, the Cohn teaching is directed to a completely different field of use, and it is not a permissible inference that micelles would form from such "small" copolymers, or that, once formed, the micelles would incorporate and deliver drugs, let alone without the need to use complex techniques such as solvent evaporation or dialysis.

The block copolymers in Cohn describe completely different properties. The teaching of Cohn, taken as a whole, relates to multiblock polymeric materials which utilize AB diblocks as building blocks for the polymeric material. See, e.g., in col 2, lines 30-32, where it is stated that the invention relates to polymeric compositions comprising coupled or crosslinked poly(ester)/polyether AB or related AB diblocks…In col 21, lines 17-20 it is stated diblocks may be used in much the same way that ACA triblocks are used in the present invention, i.e. as building polymeric units of the polymers according to the present invention, also at col 38, lines 23-27 : After synthesis of the ACA triblock or AB diblock, the final polymer is preferably obtained by chain extension. Applicants invention is a completely different field of use and is not anticipated or made obvious by Cohn.

No fees are believed due with this paper; however, should any in fact be due, the Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this Amendment to Deposit Account No. 10-0750/JAB1715USPCT/AGK/HJP

Early favorable action is respectfully requested.

Respectfully submitted,

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